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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,856	10/27/2003	Robert Yongxin	A8671	9247

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EXAMINER

SHIAO, REI TSANG

ART UNIT PAPER NUMBER

1626

DATE MAILED: 10/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/692,856

Applicant(s)

YONGXIN ET AL.

Examiner

Robert Shiao

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on responses filed on 09/09, 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 23,24,26 and 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22,25 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 02/04/04, 10/27/03.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

1. Amendment of claim 12 in the amendment filed on September 09, 2004, is acknowledged. Claims 1-28 are pending in the application.

Responses to Election/Restriction

2. Applicant's election without traverse of Group I claims 1-22, 25, and 28, in part, in the reply filed on September 09, 2004, is acknowledged.

Status of Claims

3. Claims 1-28 are pending in the application. The scope of the invention of the elected subject matter is as follows:

Claims 1-22, 25, and 28, in part, drawn to compounds and compositions of CC-1065 analogs, wherein the analogs is formed from subunit of formula (I) and (V), and R₇ of formula I is piperazino carbamate or 4-piperidino-piperidino carbamate thereof.

The invention claims 1-22, 25, and 28, embraced in above elected subject matter are prosecuted in the case. Claims 1-22, 25, and 28, in part, not embraced in above elected subject matter, and claims 23-24, and 26-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-22, 25, and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. It is noted that the claims contains subject matter "analog of CC-1065", which were not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention, i.e., see claim 1, line 1-3.

5. Claims 1-22, 25, and 28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a prodrug of an analog of CC-1065, wherein the analog formed from a first subunit of formula (I) covalently linked to a second subunit of the formula (V), does not reasonably provide enablement for a prodrug of an analog of CC-1065, wherein the analog formed from a first subunit of formula (I) covalently linked to a second subunit other than the formulae of (II)-(IX). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1988):

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- 1) Nature of invention.
- 2) State of prior art.
- 3) Level of ordinary skill in the art.
- 4) Level of predictability in the art.
- 5) Amount of direction and guidance provided by the inventor.
- 6) Existence of working examples.
- 7) Breadth of claims.
- 8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See below:

1) Nature of the invention

The claims are drawn to a compound prodrug of an analog of CC-1065 without a formula.

2) State of the prior art

The reference Chari et al. US 5,475,092 does not indicate which compounds of instant analog of CC-1065 may be useful in the claimed invention. Chari et al. '092 is pertaining to cell binding agent conjugates of analogues and derivatives of CC-1065.

3) Level of ordinary skill in the art.

The level of ordinary skill in the art is high. The claims are drawn to "a compound prodrug of an analog of CC-1065 without a formula". Applicant's

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specification does not enable the public to prepare such “a prodrug of an analog of CC-1065 without a formula” by the instant examples disclosed in the specification.

4) Level of predictability in the art.

The claims are drawn to “a compound prodrug of an analog of CC-1065 without a formula”, see claim 1, lines 1-3. Different types of the genus of compounds require various experimental procedures and without guidance that is applicable to all possible “a compound prodrug of an analog of CC-1065 without a formula”, there would be little predictability in the scope of claimed compounds.

5) Amount of direction and guidance provided by the inventor.

The claims are drawn to “a compound prodrug of an analog of CC-1065 without a formula”, encompasses a vast number of processes. Applicant's limited guidance does not enable the public to prepare such “a compound prodrug of an analog of CC-1065 without a formula” in the specification. There is no enablement for “a compound prodrug of an analog of CC-1065 without a formula”, i.e., an analog formed from a first subunit of formula (I) covalently linked to a second subunit other than the formula of (II)-(IX), which are neither enabled nor supported in the specification.

6) Existence of working examples.

The claims are drawn to “a compound prodrug of an analog of CC-1065 without a formula”, encompasses a vast number of processes. Applicant's limited working examples do not enable the public to prepare such a numerous

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amount of "a compound prodrug of an analog of CC-1065 without a formula" in the specification. Applicants claim "a compound prodrug of an analog of CC-1065 without a formula", however, the specification provides only limited examples of the compounds.

7) Breadth of claims.

The claims are extremely broad due to the vast number of possible "a compound prodrug of an analog of CC-1065 without a formula".

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The specification did not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with this claim. In particular, the specification failed to enable the skilled artisan to practice the invention without undue experimentation. The skilled artisan would have a numerous processess in order to obtain "a compound prodrug of an analog of CC-1065 without a formula" as claimed. Based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not perform the claimed compounds without undue experimentation, see *In re Armbruster* 185 USPQ 152 CCPA 1975. Incorporation of the limitation of "a compound prodrug of an analog of CC-1065", i.e., formula (I) and (V) and their covalent linking positions between formula (I) and (V), the limitation of the variable R₇ (i.e., piperazino carbamate or 4-piperidino-piperidino carbamate) of formula (I), and limitation of variable R, R₁-R₆ of formula (V), would obviate the rejection, see pages 7-10 of the specification.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-22, 25, and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 or 7, line 1, recites the limitation "comprising", is ambiguous and indefinite. It is noted that the instant compound of CC-1065 analog is drawn to an analog formed by subunit of formula (I) and (V). The instant claims recites the limitation "comprising", which is an open-end language and comprise products other than the compound of CC-1065 analog. Replacement of the limitation "comprising" with the limitation "consisting of", would obviate the rejection, see pages 7-10 of the specification.

Objection

7. Claims 1-22, 25, and 28 are objected to as containing non-elected subject matter, i.e., a phosphate of protecting group of variable R_7 of formula (I), formula (II), (III), (IV), (VI), (VII), (VIII), and (IX), etc. It is suggested that applicants amend the claims to the scope of the elected subject matter as defined on the elected subject matter of pages 2-3, *supra*.

8. Claims 17-22 are objected to as containing non-elected subject matter. It is noted that the compounds of claims 17-22 contain the non-elected subject

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matter, i.e., R₇ of formula (I) is phosphate or is not piperazino carbamate or 4-piperidino-piperidino carbamate.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

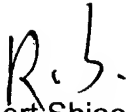
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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